K110957

As required by 21 CFR 807.92 (c) this 510(k) summary is prepared MAY 3 1 2011

Application Date:

21st Feb 2011

Applicant:

Spectrum Medical LLP
Harrier 4,
Meteor Business Park,
Cheltenham Road East,
Gloucester.
GL2 9QL
United Kingdom

Official Correspondent:

Mr Steve Turner
Chief Executive Officer
Telephone: +44 (0) 1242 650121
Fax: +44 (0) 8452 808127
Email: Steve.Turner@spectrum-medical.com

Proposed Device:

Blood Gas Monitor
Trade Name: M4 Monitor
Classification Name: Monitor, Blood-Gas, On-Line, Cardiopulmonary Bypass
21 CFR 870.4330, Product code: DRY

Predicate Devices:

K091908 Spectrum Medical - M3 Monitor.

K972962 3M - CDI 500

Description of Proposed Device:

The Spectrum M4 Monitor consists of a 10.4 inch high definition touch screen and sensor assemblies connected to a flat panel display unit. Optical sensor assemblies are used to collect data for the measurement of Arterial and Venous Saturation and Hct / Hb. Ultrasonic sensors are used to collect data for the measurement of flow and gaseous emboli. A thermistor is used for the collection of temperature data. Inlet and outlet gas measurements sensors are used to collect data for the measurement of PO_2, and PCO_2.

Parameter values are displayed in both a digital and trended format. The M4 Monitor has been designed to self-detect the selected sensor and to automatically configure

the required parameter display screens. The device can be configured by the trained clinician to set parameter specific alarms and to select either the display of hematocrit or haemoglobin concentration. Session data can be stored to a memory card supplied with the system, via a RS232 link or wirelessly to a remote computer.

The M4 Monitor is powered from the AC Mains supply and also incorporates a battery back-up that automatically switches on in the event of an interruption to the mains power supply. The system weighs 4.5 kg and is supplied with a pole mount clamp.

Intended Use of Proposed Device

The intended use of the M4 Monitor is for the non-invasive continuous monitoring of O_2 saturation, hematocrit and haemoglobin concentration, blood flow, gaseous emboli, Temperature, PO_2, and PCO_2.

The device provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarm levels.

Substantial Equivalence Determination &Technological Characteristics

Oxygen Saturation, Hematocrit / Haemoglobin Concentration, Flow & Emboli:-

The proposed device has the same technological characteristics and measurement performance as the predicate M3 monitor cleared under 510(k) K091908. Both monitor and sensor designs remain unchanged between the proposed device and the predicate M3.

Temperature PO_2 & PCO_2:-

For the measurement of Temperature, PO_2 & PCO_2 the proposed device as the same intended use as the CDI monitor cleared under 510(k) K972962 in that key measurements are made in the extracorporeal circuit during Cardiac Surgery or ECMO life support. The major difference in the technological characteristics of the proposed device and the predicate CDI 500 device is that the proposed device is completely non-invasive while the predicate device involves the use of a sterile cuvette inserted into the blood tubing.

Performance Information

The M4 Monitor has an intended use that is featured in its two predicate devices. Performance data has been provided to show that the revised M4 Monitor can measure the oxygen saturation, hematocrit / haemoglobin concentration, blood flow, gaseous emboli, Temperature, PO_2, and PCO_2.

The M4 Monitor is therefore considered substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 3 1 2011

Spectrum Medical LLP
c/o Mr. Jeff D. Rongero
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K110957
Spectrum M4 Monitor
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary bypass On-line Blood Gas Monitor
Regulatory Class: Class II
Product Code: DRY
Dated: May 25, 2011
Received: May 26, 2011

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110957

Device Name: M4 Monitor

Indications for Use:

The intended use of the M4 Monitor is for the non-invasive continuous monitoring of O_2 saturation, hematocrit and haemoglobin concentration, blood flow, gaseous emboli, Temperature, PO_2, and PCO_2, in an extracorporeal circuit.

The device provides monitoring information to trained clinicians and can be configured by them to set parameter specific alarms.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110957